

## HEALTH ECONOMIC CHECKLIST for CLINICAL TRIALS

Have you incorporated a health economic analysis/study to your trial?

- Yes, please follow [pathway A](#)
- No, please follow [pathway B](#)

Please refer to <https://www.uts.edu.au/sites/default/files/2019-04/crest-factsheet-why-economic-evaluation.pdf> if you want to know more about conducting a health economic analysis.

**Pathway A: a health economic analysis is either being considered or some rationale has been proposed that supports its consideration.**

1. What type of clinical trial is this trial?  
 Interventional  
 Observational (non-interventional)
2. What is the aim of your study (*choose all that apply*)?  
 Descriptive (i.e. systematic review of the literature)  
 Change current practice (*e.g Phase III*)  
 Construct a registry  
 Instrument validation  
 Feasibility study (*e.g Phase II, randomised Phase II*)  
 Safety (*e.g Phase I, Phase Ib*)  
 Other  
*Please specify:* \_\_\_\_\_
3. Is the intervention expected to impact the quality of life (QoL) of patients or carers?  
 Yes (*please describe how it is expected to change QoL relative to current practice*)  
 No (*go to question 5*)  
*Description:* \_\_\_\_\_
4. If differences in terms of QoL are expected, do you plan to use any generic or disease specific instrument to measure quality of life?  
 Yes  
*Which one/s:* \_\_\_\_\_  
 No
5. Have you identified any potential differences in terms of resource use between the intervention and comparator/current practice (which may result in differences in costs)?  
 Yes (*go to question 6*)  
 No (*go to question 9*)
6. What do you think is contributing to the difference in resource use (*choose all that apply*)?  
 The intervention itself.  
 Differences in the incidence of AEs which lead to differences in management, hence costs.  
 Differences in the management of the disease other than the intervention.  
 The intervention is expected to prolong life; hence patients are expected to incur more healthcare costs.  
 Differences in concomitant medications.  
 Differences in required procedures.  
 Differences in numbers of cases detected (for diagnostic interventions).
7. Do you think patients incur costs beyond health-related costs (i.e. time, carers, productivity, etc.)?  
 Yes  
 No
8. Are you considering asking patients for consent to access their Medicare data (MBS & PBS) and/or hospital record data to identify resource use?  
 Yes  
 No
9. In the context of this research, are you interested in knowing the preferences of patients or carers for the treatment options being compared in the trial?  
 Yes  
 No

**Recommendation:**

*If you answered **yes** to questions 3, 5 and/or 9, please contact your CTG to request a health economics audit for this study.*

**Pathway B: a health economic analysis is not currently being considered, but it would be helpful to assess whether it might be relevant.**

1. What type of clinical trial is this trial?

- Interventional
- Observational (non-interventional), go to question 5.

2. What is the aim of your study (*choose all that apply*)?

- Descriptive (i.e. systematic review of the literature)
- Change current practice (*e.g Phase III*)
- Construct a registry
- Instrument validation
- Feasibility study (*e.g Phase II, randomised Phase II*)
- Safety (*e.g Phase I, Phase Ib*)
- Other

*Please specify:*

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3. Is the intervention expected to impact the quality of life (QoL) of patients or carers?

- Yes (*please describe how it is expected to change QoL relative to current practice*)
- No

*Description:*

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4. Have you identified any potential differences in terms of resource use between the intervention and comparator/current practice (which may result in differences in costs)?

- Yes (*please provide description below*)
- No (*go to question 5*)

*Description:*

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5. Have you planned to collect data regarding resource use related to the intervention?

- Yes
- No

6. In the context of this research, are you interested in knowing about the preferences of patients or carers for the alternative treatment options in the trial?

- Yes
- No

**Recommendation:**

*If you answered **yes** to questions 3, 4, and/or 6, please contact your CTG to request a health economics audit for this study.*